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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,942	05/04/2005	Enrico Garaci	ARC-4865-45	9693
23117 NIXON & VA	7590 03/24/200 NDERHYE, PC	EXAMINER		
901 NORTH G	LEBE ROAD, 11TH F	ZAREK, PAUL E		
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/533,942	GARACI ET AL.		
Office Action Summary	Examiner	Art Unit		
	Paul Zarek	1617		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D. Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
Responsive to communication(s) filed on <u>28 Jac</u> This action is FINAL . 2b) ☑ This Since this application is in condition for alloware closed in accordance with the practice under Expression in the Expression in t	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o Application Papers 9) ☐ The specification is objected to by the Examine	wn from consideration. r election requirement.			
10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Expression of the second	epted or b) objected to by the I drawing(s) be held in abeyance. See cion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate		

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/28/2009 has been entered.

Status of the Claims

2. Claims 10-12 have been cancelled by the Applicant in correspondence filed on 01/28/2009. Claims 4-9 are currently pending. This is the first Office Action on the merits of the claim(s) following a request for continued examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Italian patent application RM2002A000562 (filed on 11/06/2002) has was received on 10/15/2008. The foreign priority of the instant application is 11/06/2002.

RESPONSE TO ARGUMENTS

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4. Claims 10-12 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is moot in light of Applicants' cancellation of Claims 10-12.

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5. Claims 4-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heredia, et al. (Journal of Acquired Immune Deficiency Syndromes, 2000) in view of Kurokawa, et al (Journal of General Virology, 1990, and Pätzold, et al. (Antiviral Research, 1993). Applicants traversed this rejection on the grounds that the art cited does not render obvious the claimed invention. Specifically, Applicants allege that Heredia, et al., and Pätzold, et al., teach that resveratrol (Heredia, et al.) or a PKC inhibitor (Pätzold, et al.) inhibit HIV replication, and not influenza replication. Applicants note that HIV and influenza are distinct RNA viruses, possessing different life cycles. Thus, one of ordinary skill in the art would not reasonably expect that a treatment for HIV would necessarily treat influenza, and vice versa. Applicants also allege that Kurokawa, et al., do not teach that inhibiting PKC would inhibit influenza viral growth, and that the mechanism of the inhibitory effect of the PKC inhibitor, H7, on influenza is, or may be related to some as yet unknown property of H7. Examiner finds the Applicants' arguments persuasive. Thus, the rejection of Claims 4-9 under 35 U.S.C. 103(a) as being unpatentable over Heredia, et al., in view of Kurokawa, et al., and Pätzold, et al., is withdrawn.

Below are listed new grounds of rejection that are <u>not</u> necessitated by amendment to the claims.

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Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S.C. 03(a) not included in this action can be found in a prior Office action.

- 7. Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Root, et al. (Journal of General Virology, 2000), in view of Stewart, et al. (Biochemistry, 1999), and Heredia, et al. (above).
- 8. Claims 4 and 7 are drawn to a method of inhibiting influenza virus replication (Claim 4) or treating an influenza infection (Claim 7) comprising administration of resveratrol. Claims 5 and 8 limit the subject to a human and the influenza virus to human influenza virus. Claims 6 and 9 limit the subject to a veterinary animal and the influenza virus to a veterinary virus infection.
- 9. Root, et al., teach that the inhibiting PKC inhibited influenza viral replication and that the "activity of PKC is crucial for influenza virus entry, and may be a target for future antiviral therapy" (pg 2698, paragraph bridging col 1 and 2). Thus, Root, et al., meet the claim limitations of inhibiting influenza viral replication and treating an influenza infection. Root, et al., do not teach the antiviral properties of resveratrol.
- 10. Stewart, et al., teach that resveratrol inhibits PKC (pg 13245, col 1, paragraph 1, lines 1-
- 3). Taken together, Root, et al., and Stewart et al., teach that resveratrol would be an effective anti-influenza agent. Neither Root, et al., nor Stewart, et al., provide a motivation to use resveratrol to inhibit influenza replication or to treat influenza infections in humans or a veterinary animal.

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11. Heredia, et al., teach that resveratrol is a natural "a widely used natural product," indicating that it is already safely used, *in vivo*, and can be obtained at a low-cost (pg 247, col 1, final paragraph). This would provide motivation for a skilled artisan to utilize for the inhibition of influenza replication or treating an influenza infection.

12. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use resveratrol, a known PKC inhibitor, which is safe for *in vivo* use and can be obtained at a low cost, for the inhibition of influenza replication and treatment of influenza infection.

Conclusion

- 13. Claims 4-7 are rejected.
- 14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/ Primary Examiner, Art Unit 1625